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| 09/143,379 | 08/28/1998 | R. RAO KOGANTY | 042881/0119 | 3442 |

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EXAMINER

WESSENDORF, TERESA D

| ART UNIT | PAPER NUMBER |
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1639

DATE MAILED: 10/20/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/143,379

Applicant(s)

KOGANTY ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2001 and 05 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

Claims 1-44 are pending.

Claims 1-31 and 39-41 are withdrawn from consideration as being drawn to non-elected invention.

Claims 32-38 and 42-44 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-38 and 42-44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the combinatorially generated glycopeptide library according to the present invention will contain a large number of new compounds, many of which will have useful biological activity.

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In response, applicants are not claiming the new compounds present in the library, but the library per se. It is the library which has no specific or well-established utility.

It is argued that the examiner's statement that the library is a collection of known or existing products that need to be screened to disclose a new compound contained therein is contradictory.

In response, there is nothing contradictory about this statement. Rather, the statement is based on applicants' Examples in the specification. The examples show the mixing of known compounds to discover a new inhibitor.

It is argued that MPEP 2107 clearly states that inventions that are useful in a research setting may indeed have a clear, specific and unquestionable utility such as research tools as screening assays and nucleotide sequencing techniques. Applicants submit that a combinatorially-generated glycopeptide library is just such a tool, and thus patentable under 101.

In response, MPEP 2107 defines research tools as gas chromatographs, screening assays and nucleotide sequencing techniques. Nowhere in the MPEP section has a library been included. Even assuming, for the sake of argument, that the library is a tool use for screening however, it is not seen how screening (not, a screening assay) can be done with the instant

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combinatorial library given no structure for said library. The library is only characterized by the process by which it is made.

Applicants argue that skilled artisan need not go "hunting" to find a combinatorially-generated glycopeptide according to the invention. The specification clearly places such a library in the hands of the public, where it will provide a useful tool in identifying biologically active compounds.

In response, a skilled artisan need not go hunting for a library since this library can be the naturally occurring product. Hunting is used in the context, not as argued. Rather, "hunting" is used in the context of searching a specific utility for the library. At the time of applicants' invention, the patent application is incomplete as searching the utility for the library is not a specific or definite utility. It has not **successfully accomplished** a specific, substantial and well-established utility for said library. Rather, it has to be screened, like any collections of products, things or any other kind of naturally or non-naturally collections. This screening (assay) results in the isolation of a product that hopefully, will have a specific and substantial utility.

Applicants argue that the USPTO has granted other patents with claims to combinatorial libraries, including very large

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combinatorial libraries. USP 5,738,996 and USP 6,268,160 are cited (the copies of the claims are alleged to be attached).

In reply, no copy of the claims is attached to the instant REMARKS. Nevertheless, it is well settled that a case is treated on its own merits i.e., on a case-to-case basis.

Applicants argue that the examiner appears to fear that granting a claim to such a library would grant to applicants rights in each and every useful compound contained in such a library, thus precluding others from isolating, identifying and patenting specific compounds in such a library.

In reply, it not for the reason as argued above that a patent is not granted for a library. Rather, as applicants seemed to admit, it is the compound in the library that is useful, and not the library itself. The library has to be "hunted" for a specific compound, which is the one, which is useful under the statute.

Claims 32-38 and 42-44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See the 101 rejection, above.

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Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-38 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

Response to Arguments

The rejection of claim 38 under this paragraph is withdrawn, in view of applicants' arguments. However, the rejection under paragraph B is maintained as set forth below.

B). Applicants argue that armed with applicants' disclosure of how to produce a combinatorial glycopeptide library, a skilled artisan readily could select platforms and carbohydrates to produce a library of compounds likely to contain some with of the recited activities.

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In response, applicants fail to specifically point out the relevant section applicants are relying on. Thus, it is not clear as to the method that a skilled artisan needs to employ to accomplish which of the different opposing activities the library possesses.

Applicants have not addressed the rejection with respect to the specification not adequately describing a carbohydrate structure that function as adhesion ligands for bacterial receptors expressed on human cell surface antigens. Since applicants have not addressed this rejection, it is believed that applicants are acquiescing therewith.

Claims 32-38 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mucin 1 (MUC1) as the core protein and inhibitory activity for a compound in the library, does not reasonably provide enablement for the broadly recited combinatorially-generated library of glycopeptides for reasons of record.

Response to Arguments

Applicants argue that in a combinatorial approach, the skilled artisan need not be concerned with how or where moieties are attached. The beauty of a combinatorial process is that it generates all permutations automatically, and then an automated large-scale screening assay can be used to identify useful compounds. There is widespread interest in using combinatorial

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libraries of random-sequence oligonucleotides, polypeptides or synthetic oligomers to search for biologically active compounds.

In response, there is nothing in the specification that describes an automated large-scale screening assay for a combinatorial library containing all conceivable permutations. Furthermore, as applicants state the widespread interest in the use of libraries is drawn to oligonucleotides, polypeptides or synthetic oligomers, and not to the instant glycopeptides.

Applicants further argue that very large numbers of compounds can be screened easily to provide a manageable subset of useful compounds, and the skilled artisan can then study these useful compounds to elucidate their structure. The experimentation involved is not undue and combinatorial approaches have been used with other types of compounds.

In response, as stated by applicants combinatorial approach has been used for other compounds, and not for the instant compounds which applicants claimed is new. Furthermore, the library compounds do not recite for a structure. Hence, it is not clear as to the kind of glycopeptides that can be subject to the argued assay, especially in the absence of positive support in the specification. The specification provides guidance only for the glycopeptide i.e., MUC1 as the core protein to which a random glycosyl components can be attached. No other core or scaffold protein to which any library of glycosyls can be attached. More importantly, there is no screening method that

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identifies each of the different functions that is supposedly possessed or can be achieved by the library. Furthermore, the examples specifically describe a specific type of glycopeptide library that employs a specific type of assays for the glycopeptide inhibitory activity. In view of the statement provided by applicants that a hit may not be produced from a large library, the claimed invention is not enabled for its broad scope. See also applicants' Remarks at paragraph bridging pages 8 and 9 of the instant RMARKS.

Claim Rejections - 35 USC § 112, second paragraph

Claims 32-38 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that there is no other way to claim a combinatorial library. A combinatorial library by definition contains compounds the identity of which is unknown at the time the library is generated.

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In reply, as shown in the specification, its structure, which can be random or biased, in part or whole depending upon the parent compound from which the library is derived can identify a library. In the instant case, the MUCINS-associated compounds. See applicants REMARKS at page 9, first complete paragraph.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: combinatorially-generated glycopeptide library. The specification describes a combinatorial glycopeptide library, not a combinatorial generation of said library.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32, 34-38 and 42-43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al (5,795,958) for reasons advanced in the last Office action.

Response to Arguments

Applicants admit that Rao discloses a collection or library of glycopeptide. Nevertheless, argue that Rao (col. 3, lines 15-17) discloses that each glycopeptide is individually synthesized using a multicolumn automated peptide synthesizer by sequentially coupling individual amino acids including pre-fucosylated serine and subsequently combined to form a collection of library. And, further argue that Rao does not disclose a combinatorially-generated library of randomly glycosylated structures and thus the so-called "library" is not the same product. Rao is further argued not to possibly be alleged to disclose libraries that would have the size and

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diversity of the libraries claimed by applicants and thus, cannot reasonably be said to disclose a product that is the same or similar to applicants' claimed library.

In response, the specification does not describe a combinatorially generated random library. There is nothing that differentiates this library from the instant random library of glycopeptides. The steps recited in the claims of preparing the library of glycopeptide by randomly reacting a peptide scaffold with a carbohydrate structures that function as adhesion ligands for bacterial receptors is the same random library of Rao. See e.g., col. 7, line 60 to col. 8, line 11. Whether the library of Rao is produced by sequential coupling of individual amino acids as opposed to the instant random reaction is immaterial as the same library product is obtained by Rao. [Note that Rao also discloses said random reaction]. Applicants' further arguments as to the differences in size and diversity of the instant library from the glycopeptide library of Rao are not commensurate in scope with the claims. The claims do not recite for a library size or any diversity in the library. Contrary to applicants' arguments, Rao discloses at e.g., col. 21, lines 44-49 not only variations in the amino acid residues but also variations in the multiple carbohydrate residues of the peptide derivatives. The carbohydrate residues that can be varied include N-acetylgalactosamine, inter alia.

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Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

Claims 32 and 34-38 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vetter et al (WO 95/18971) for reasons set forth in the last Office action.

Response to Arguments

Applicants argue that Vetter, as in Rao, the library is limited, and not the same as the combinatorially library presently claimed.

In reply, the response under Rao above is incorporated herein.

Claims 32 and 34-38 are rejected under 35 U.S.C. 102(a) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schleyer et al (Angew. Chem. Int.) for reasons of record.

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In view of the amendments to the specification claiming priority to the provisional application, the rejection of the claims under Scheleyer is withdrawn.

Claims 32-37 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frische et al (abstract of J. Pept. Sci.).

Response to Arguments

Since applicants merely apply the same arguments under Rao above hence, the response under Rao and Vetter above is applied herein.

Applicants' further arguments as to the size and diversity produced by the combinatorial libraries as exemplified by MUC3 are noted. However, none of the claims recite for MUC3. Rather, the claims recite for MUC1.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

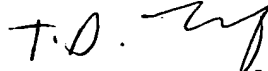
This application contains claims 1-31 and 39-41 drawn to nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
October 16, 2003